UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SPECGX LLC, Plaintiff, v. BARBARA D. UNDERWOOD, in her official capacity as acting Attorney General of the State of New York; and HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of the State of New York, Defendants.	No. 1:18-cv-09830-KPF **Oral Argument Requested**

PLAINTIFF SPECGX LLC'S COMBINED OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND REPLY IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

PRELIMINARY STATEMENT

What is most notable about Defendants' response to SpecGx's motion for a preliminary injunction and motion to dismiss is how much of SpecGx's argument they concede. Defendants do not dispute that the Opioid Stewardship Act ("OSA") imposes a financial "surcharge" on manufacturers of FDA-approved generic opioid medications that exceeds even the wholesale *prices* of those products, let alone any profit after accounting for the costs of production and distribution. Nor do they dispute that the OSA's "pass on" prohibition precludes SpecGx from collecting the surcharge from the New York purchasers of those same products. Everything else in SpecGx's suit, including finding the OSA unconstitutional under the Supremacy and dormant Commerce Clauses, follows ineluctably from those central, undisputed facts.

The necessary consequence of the size of the surcharge in combination with the volume-based calculation method and the "pass on" prohibition is that generic opioid manufacturers will lose money on each sale of their generic opioid products in New York, with the inevitable consequence being that generic manufacturers will cease those sales, as SpecGx is already planning to do. Defendants concede that Congress's purpose in enacting the Hatch-Waxman Amendments was to facilitate the entry of generic medicines into the market, in order to *increase* the availability to patients of affordable generic medications. It necessarily follows from these undisputed facts, under settled Supreme Court precedent, that the OSA is preempted by federal law. The OSA stands as an obstacle to accomplishing the purposes of the Hatch-Waxman Amendments because the OSA will drive generic products from the market, leaving high-priced branded products with an effective monopoly, in contravention of Congress's purposes.

Rather than meet these arguments head-on, Defendants engage in misdirection. Defendants mischaracterize the OSA's Ratable Share as a mere "tax" that might "erode" profits,

decrease sales, or cause similar "inconveniences." *See* Defs.' Mem. of Law in Supp. of Mot. to Dismiss and Opp'n to Pl.'s Mot. for Prelim. Inj. ("Defs.' Mem.") at 1–2, 15. But the undisputed record is to the contrary—the OSA does not merely "reduce" profits on generic opioids; it forces sales to occur at a loss, which will drive generic products from the market. Defendants' wholly speculative suggestion that SpecGx can offset the losses from other sales, *see* Defs.' Mem. 17, both misreads the OSA (to the extent it suggests New York pharmacies can be forced to shoulder the Ratable Share burden) or implicitly embraces shifting the burden to out-of-state sales in violation of the dormant Commerce Clause (to the extent Defendants suggest the losses would be offset by SpecGx's nationwide profits).

Unable meaningfully to dispute the substance of SpecGx's constitutional claims, Defendants raise a series of threshold challenges to SpecGx's lawsuit, urging that this is the wrong court, the wrong time, and the wrong party to raise these claims. Not so.

First, this Court can and should exercise jurisdiction here. This is not a matter of state taxation that should be left to New York state courts to resolve, by virtue of the Tax Injunction Act or any other theory of abstention. The OSA imposes Ratable Shares on SpecGx and other manufacturers and distributors of pharmaceutical products and then prohibits manufacturers and distributors from passing on the cost of the Ratable Share to purchasers. This is a penalty enacted pursuant to the State's police power, not a tax. And this penalty violates the *federal* constitution. This is not a matter of state taxation, but one of federal constitutional protections, and this court is the most appropriate venue to consider these challenges. Indeed, SpecGx's federal preemption challenge is, in particular, more appropriate to be heard by this Court, rather than a state court.

Second, SpecGx needs relief from the OSA immediately. Not only is its $1.2 million Ratable Share due in just six weeks, but given recent communications from its three major

distributors that they will pass their Ratable Share payments up to their manufacturers, SpecGx is planning to exit the market to avoid selling its generic opioid products at a loss.

Third, SpecGx has standing to bring its dormant Commerce Clause challenge. It is not asserting claims on behalf of out-of-state purchasers or manufacturers with out-of-state facilities. At issue is whether *SpecGx* would be forced to pass the Ratable Share costs outside of the state.

Lastly, SpecGx stands to be irreparably harmed by the imposition of Ratable Shares and the inability to pass on this cost to its purchasers. This imposition constitutes a constitutional injury, which by itself is irreparable harm. But beyond that, SpecGx also stands to suffer monetary damages that it would be barred from recovering from state officials for its "pass on" prohibition losses and also nonmonetary injuries related to the loss of goodwill and business relationships and opportunities that will occur when SpecGx is forced to exit the New York market. These concerns, not to mention the detrimental effect on patients in the state of New York who will have limited access to affordable FDA-approved generic opioid medications for which DEA has determined there is legitimate need, far outweigh any countervailing burdens to Defendants.

* * *

Defendants make no effort to challenge the factual recitation in SpecGx's opening brief. In opposition to Defendants' Motion to Dismiss, SpecGx refers the Court back to the factual background set forth in SpecGx's memorandum in support of its motion for preliminary injunction.

ARGUMENT

I. DEFENDANTS' THRESHOLD ARGUMENTS FAIL TO RAISE ANY IMPEDIMENT TO THE COURT'S CONSIDERATION OF SPECGX'S CLAIMS

Defendants raise a series of threshold jurisdictional challenges to SpecGx's lawsuit—including many of the same ones Defendants raised in the related actions by Healthcare Distribution Alliance ("HDA") and the Association for Accessible Medicines ("AAM") (the

"Related Actions").[1] *See* Defs.' Mem. at 6. HDA and AAM have convincingly explained why these threshold challenges fail, and SpecGx expressly incorporates by reference HDA's and AAM's responses to Defendants' challenges.[2] SpecGx here highlights why Defendants' arguments are particularly misplaced in the context of SpecGx's distinct claims. For the reasons discussed below, and in HDA's and AAM's responsive briefing, none of the recited "threshold jurisdictional defenses" imposes any impediment to this Court's consideration of SpecGx's claims.

A. The Tax Injunction Act Is Inapplicable

The Tax Injunction Act ("TIA"), which instructs that district courts "shall not enjoin, suspend or restrain the assessment, levy or collection of any tax under State law where a plain, speedy and efficient remedy may be had in the courts of such State," 28 U.S.C. § 1341, does not foreclose this action for two independent reasons. *First*, the Ratable Share imposed by the OSA is not a tax and, therefore, the TIA has no application to any of HDA, AAM, or SpecGx's challenges.[3] *Second*, even if the TIA were otherwise applicable, SpecGx's particular claims arise solely from the OSA's "pass on" prohibition. The prohibition against passing the surcharge on to purchasers is plainly not an "assessment, levy or collection of any tax," but rather an exercise of the State's police power, and striking the "pass on" prohibition would not threaten the State's collection of any funds. *See infra* Part I.A.2; AAM Resp. MTD 6–9. Whether on the basis of the broader or narrower rationale, the TIA does not deprive the Court of authority to grant relief on SpecGx's claims.

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[1] The Related Actions have a common factual and legal nucleus with this action.

[2] Combined Opposition to Defendants' Motion to Dismiss and Reply in Support of Plaintiffs' Motion for Summary Judgment, *Healthcare Distribution Alliance v. Zucker*, No. 18-cv-06168 (S.D.N.Y. Nov. 7, 2018) ("HDA Mem."); Opposition to Defendants' Motion to Dismiss, *Ass'n for Accessible Medicines v. Underwood*, No. 18-cv-08180 (S.D.N.Y. Nov. 7, 2018) ("AAM Resp. MTD"); Reply in Support of Plaintiff's Motion for Preliminary Injunction, *Ass'n for Accessible Medicines v. Underwood*, No. 18-cv-08180 (S.D.N.Y. Nov. 7, 2018) ("AAM Reply PI").

[3] *See infra* Part I.A.1; AAM Resp. MTD 4–10; HDA Mem. 2–9.

1. The Ratable Share Imposed by the OSA Is Not a Tax.

Because there is no "tax" at issue here, the TIA is wholly inapplicable. Both in name and in substance, the Ratable Share is not a tax.

The plain language of the OSA avoids the term "tax," speaking only of "stewardship payments" and a "ratable share." N.Y. Pub. Health Law § 3323 (McKinney 2018). Defendants cite *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) ("*NFIB*"), as authority for the proposition that the OSA amounts to a tax, despite the OSA's own terminology.[4] Defendants cite the portion of the Court's opinion holding that, for purposes of constitutional analysis, the Affordable Care Act's charge imposed on those without insurance was a permissible exercise of Congress's taxing authority. *Id.* (citing *NFIB*, 567 U.S. at 567–68). But the Court expressly distinguished its constitutional holding from its holding as to whether the charge was a "tax" for purposes of the Anti-Injunction Act ("AIA"). *NFIB*, 567 U.S. at 543–47. With respect to the latter, the Court read the word "tax" in the AIA to mean "statutorily described 'taxes.'" *Id.* at 544. As the Court explained, "the best evidence of Congress's intent is the statutory text." *Id.* Even though the Court-appointed amicus contended that "though Congress did not label the shared responsibility payment a tax, [courts] should treat it as such under the Anti-Injunction Act because it functions like a tax," the Supreme Court took Congress at its word and refused to treat the shared responsibility payment as a statutory tax. *Id.* The TIA "was modeled on the Anti-Injunction Act . . . [and courts] assume that words used in both Acts are generally used in the same way." *Direct Mktg. Ass'n v. Brohl*, 135 S. Ct. 1124, 1129 (2015). Applying the relevant holding of *NFIB* to the TIA, this Court should take the New York Legislature at its word and recognize that the

[4] Memorandum of Law in Support of Defendants' Motion to Dismiss at 6, *Healthcare Distribution Alliance*, No. 18-cv-06168 (Oct. 17, 2018); *see also* Memorandum in Support of Defendants' Motion to Dismiss at 8, *Ass'n for Accessible Medicines*, No. 18-cv-08180 (Oct. 17, 2018).

OSA's Ratable Share or "stewardship payment" (like the ACA's "shared responsibility payment") was carefully drafted to avoid characterizing the payment as a tax, and, therefore, should not be treated as such.

Moreover, HDA and AAM explain why the OSA fails the test set forth in *Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, 737 F.3d 228, 231–32 (2d Cir. 2013), for determining whether a payment qualifies as a tax. Under the OSA, the funds are for a special purpose rather than the general fisc, HDA Mem. 5–6; AAM Resp. MTD 9–10, and are controlled by the Department of Health and the Office of Alcoholism and Substance Abuse Services rather than the treasury, AAM Resp. MTD 9. Notably, *Entergy* approvingly cited *San Juan Cellular Telephone Co. v. Public Service Commission of Puerto Rico*, 967 F.2d 683 (1st Cir. 1992), whose additional insights "reinforce the conclusion" that the OSA is not a tax. *Entergy*, 737 F.3d at 232. In *San Juan Cellular*, then-Judge Breyer framed the distinction between a tax and a regulatory fee:

> The classic "tax" is imposed by a legislature upon many, or all, citizens. It raises money, contributed to a general fund, and spent for the benefit of the entire community. The classic "regulatory fee" is imposed by an agency upon those subject to its regulation. It may serve regulatory purposes directly by, for example, deliberately discouraging particular conduct by making it more expensive. Or, it may serve such purposes indirectly by, for example, raising money placed in a special fund to help defray the agency's regulation-related expenses.

967 F.2d at 685 (citations omitted). The First Circuit there held that a 3% charge on a private phone company was a fee not a tax because "[a] regulatory agency assesses the fee," "the agency places the money in a special fund," and "[t]he money is not used for a general purpose but rather to [defray agency expenses and fund its programs]." *Id.* at 686. The OSA fits comfortably within this definition of a regulatory fee: Ratable Shares are imposed on "those subject to its regulation" (*i.e.*, "Licensees") and are not deposited into the State's general fund, but are instead placed in a special fund subject to the control of the Commissioner of the Office of Alcoholism and Substance Abuse Services and the Commissioner of the Department of Health. Moreover, the fund supports

programs operated by those agencies, N.Y. State Fin. Law § 97-aaaaa, and may not be used for other purposes except with express approval by either Commissioner (or their designees). *Id*. Taken together, these features demonstrate that the OSA is not a tax. *See San Juan Cellular*, 967 F.2d at 686.

Because the OSA does not establish a tax, the three suits to enjoin it are not subject to the strictures of the TIA in any way.

2. In Any Event, SpecGx's Challenge Does Not Seek to Restrain an Assessment, Levy, or Collection.

Even if the OSA's "ratable share" qualified as a tax under the TIA, the TIA would not in any way foreclose the Court's ability to issue an injunction against the OSA's "pass on" prohibition. AAM Resp. MTD 6–8 (explaining why such an injunction would not affect the assessment, levy, or collection of Ratable Shares). As SpecGx's Complaint and request for a preliminary injunction make clear, the feature of the OSA that has the practical effect of either driving generic opioid medications out of the New York market (in violation of the Supremacy Clause) or forcing SpecGx to pass the surcharge on to out-of-state purchasers (in violation of the dormant Commerce Clause) is the OSA's prohibition against passing the surcharge on to SpecGx's New York purchasers. Thus, an injunction against enforcement of the "pass on" prohibition would remedy the distinctive claims asserted in SpecGx's Complaint.[5]

The Second Circuit has dealt with "pass on" prohibitions before and has repeatedly permitted challenges to them in federal court notwithstanding the TIA. In *Mobil Oil Corp. v. Tully*, 639 F.2d 912 (2d Cir. 1981), a New York law stated that the state assessment and penalty "shall

[5] As noted in SpecGx's Complaint, SpecGx also agrees with the claims separately asserted by HDA and AAM in their complaints. HDA has explained why the OSA constitutes a legislative penalty imposed without due process of law and in violation of the prohibition on bills of attainder. For the reasons explained in I.A.1 above, the TIA would not preclude an injunction against the OSA in its entirety as warranted by those meritorious claims.

not be included, directly or indirectly, in the sales price of [a company's] products." *Id*. at 913. In *Mobil Oil Corp. v. Dubno*, 639 F.2d 919 (2d Cir. 1981), Connecticut prohibited raising prices of certain petroleum products by an amount greater than the average amount the company raised those products' prices on the East Coast. *Id.* at 920. In both cases, the Second Circuit explained that such provisions are "not an exercise of a taxing power but a police power affecting the price structure of . . . products." *Tully*, 639 F.2d at 918 ("[I]n barring the [oil companies] from recovering their costs from the consumer directly or indirectly, the State has gone beyond its taxing powers and has employed its police powers."); *see also Dubno*, 639 F.2d at 922 (holding the Connecticut statute's "pass on" prohibition was "not an exercise of the state's taxing power"). And in both of those cases, the Second Circuit held that the TIA did not prevent it from enjoining the "pass on" prohibitions at issue because the prohibitions had nothing to do with the states' collection of money. *Dubno*, 639 F.2d at 922 (holding injunction of "pass on" prohibition "did not seek to restrain the assessment, levy or collection of a tax" because the assessment was "continuing to accrue and be collected"); *Tully*, 639 F.2d at 918 (explaining that the TIA was inapplicable because plaintiffs "do not challenge the imposition of the tax, or the rate of the tax, or the allocation formula on the collection of the tax").

Accordingly, where (as here) the challenge is limited to the "pass on" prohibition, "it cannot seriously be argued that [any injunction on the "pass on" prohibition] has enjoined, suspended or restrained the assessment, levy or collection" of any tax, because New York can continue to collect the Ratable Share without the prohibition. *Dubno*, 639 F.2d at 922. Thus, the TIA does not prevent this Court from enjoining the "pass on" prohibition here.

Defendants' concern that the State would be forced to pay for any increase in price and therefore the surcharge would be of little use, Defs.' Mem. 2, conflates New York's role as tax

collector and its role as purchaser. The State could make the same complaint about any producer of a good that it purchases: as a purchaser of petroleum, the State would lose some of the revenue it raises from a surcharge on petroleum. Yet in *Dubno* and *Tully*, the Second Circuit made clear that the TIA did not prevent the court from issuing an injunction against a prohibition on passing through a surcharge on oil. *See Dubno*, 639 F.2d at 922; *Tully*, 639 F.2d at 918; *see also Direct Mktg. Ass'n v. Brohl*, 135 S. Ct. at 1131 ("The TIA is keyed to the acts of assessment, levy, and collection themselves . . . ."). Because any injunction of the "pass on" prohibition would affect only SpecGx's ability to collect its share of the OSA payments from New York purchasers, and not New York's ability to assess and collect the Ratable Share, the TIA does not apply to SpecGx's challenge.

B. Principles of Comity and *Pullman* Abstention Are Inapplicable to SpecGx's Federal Law Challenges to the OSA

In addition, Defendants contend that the Court should dismiss this case under principles of comity or *Pullman* abstention, because the OSA constitutes "a critical matter of State policy" and "New York courts have not yet had an opportunity to pass" on the OSA's interpretation. Defs.' Mem. 2. Nevertheless, because *federal* claims form the fabric of SpecGx's claims, Defendants' state-specific prudential concerns miss the mark.

1. Principles of Comity Are Not at Play

Defendants first point to principles of comity as a basis to deny federal review of SpecGx's challenges to the OSA. Defs.' Mem. 2. Defendants' comity argument, however, ignores the uniquely federal character of SpecGx's claims. *See* HDA Mem. 9–11; AAM Resp. MTD 11–14.

Abstention under comity principles "manifest[s] federal respect for State law and policy." *In re Pan Am. Corp.*, 950 F.2d 839, 846 (2d Cir. 1991). But "[w]hen the applicable substantive law is federal, abstention is disfavored." *De Cisneros v. Younger*, 871 F.2d 305, 308 (2d Cir.

1989). Indeed, SpecGx's primary claim is that the OSA is preempted by federal law, and abstention "is *not* appropriately invoked in a preemption case," because "supremacy clause questions are 'essentially one[s] of federal policy.'"[6] *In re Pan Am. Corp.*, 950 F.2d at 847 (emphasis added). The OSA directly frustrates supreme federal statutory policy, rendering any comity-related deference unwarranted.

2. Pullman *Abstention Has No Application Here*

In the alternative, Defendants urge abstention under the doctrine of *Railroad Commission of Texas v. Pullman Co.*, 312 U.S. 496 (1946). Defs.' Mem. 2. The Second Circuit has "abstained under *Pullman* 'when three conditions are met: (1) an unclear state statute is at issue; (2) resolution of the federal constitutional issue depends on the interpretation of the state law; and (3) the law is susceptible 'to an interpretation by a state court that would avoid or modify the federal constitutional issue.'" *Hartford Courant Co. v. Pellegrino*, 380 F.3d 83, 100 (2d Cir. 2004) (quoting *Vt. Right to Life Comm., Inc. v. Sorrell*, 221 F.3d 376, 385 (2d Cir. 2000)). But "[e]ven when these conditions are fulfilled, [courts] are not required to abstain, and, to the contrary, 'important federal rights can outweigh the interests underlying the *Pullman* doctrine.'" *Id.* (quoting *Vt. Right to Life Comm., Inc.*, 221 F.3d at 285). To that end, the "abstention doctrine is *not* usually applied in a case involving a preemption claim." *Christ the King Reg'l High Sch. v. Culvert*, 815 F.2d 219, 223 n.4 (2d Cir. 1987) (emphasis added). Defendants have shown no reason to deviate from the general presumption *against* abstention in the face of a preemption claim, such as the one SpecGx asserts here.

[6] For that reason, federal courts routinely recognized that preemption claims provide good reason for federal review. *See United Mine Workers of Am. v. Gibbs*, 383 U.S. 715, 727 (1966) (providing as an example of "particularly strong" situations where a federal court should assume jurisdiction those "closely tied to questions of federal policy . . . . [*e.g.*, one that] implicates the federal doctrine of pre-emption").

Nor can Defendants demonstrate that the *Pullman* factors would otherwise favor abstention, because SpecGx's federal constitutional claims will remain regardless of any state court's construction of the OSA. Defendants attempt to turn the vagueness of the OSA's penalty provisions into a factor favoring the state, Defs.' Mem. 8, 16–17, but this is actually an independent constitutional infirmity, as explained by HDA. First Am. Compl. for Decl. and Inj. Relief ¶¶ 95–105, *Healthcare Distribution Alliance v. Zucker*, No. 18-cv-06168 (S.D.N.Y. Aug. 22, 2018); HDA Mem. 25–27. In any event, ascertaining the precise contours of the penalty provision or any of the other particular aspects of the statute to which Defendants point have no relevance to whether the OSA, in light of its "pass on" prohibition, violates the Supremacy Clause and the dormant Commerce Clause, as challenged by SpecGx. There is no ambiguity as to the essential facts that the OSA imposes a surcharge on generic opioid manufacturers that exceeds even the price of their product, and precludes manufacturers from passing that cost on to their purchasers.[7] The OSA states: (i) "[n]o licensee shall pass the cost of their ratable share to a purchase, including the ultimate user of the opioid," N.Y. Pub. Health § 3323(2); and (ii) "[w]here the ratable share, or any portion thereof, has been passed on to a purchaser by a licensee, the commissioner may impose a penalty not to exceed one million dollars per incident," *id.* § 3323(10)(c) (emphasis added). While there may be ambiguity as to certain aspects of the OSA's application, the core prohibition is clear; ambiguities at the periphery "cannot avoid the necessity for constitutional adjudication." *Naprstek v. City of Norwich*, 545 F.2d 815, 818 (2d Cir. 1976).

Nor can state-based questions of severability deprive SpecGx of a federal forum, *see* Defs.' Mem. 20, because severability operates as a "remedial question," *United States v. Booker*, 543

[7] Defendants' attempt to rewrite the "pass on" prohibition to permit passing on the cost of the Ratable Share to in-state purchasers of non-opioid medications fails for the reasons discussed *infra*.

U.S. 220, 263 (2005), separate and distinct from the resolution of SpecGx's federal issues. According to the OSA's own terms, any severability analysis would occur *only after* an adjudication of invalidity. *See* N.Y. Sess. Laws ch. 57, pt. NN, § 4 (McKinney) ("If any clause, sentence, paragraph, subdivision, or section of this act *shall be adjudged* by any court of competent jurisdiction *to be invalid*." (emphasis added)). And the OSA plainly declares that it "would have been enacted even if such invalid provisions had not been included therein." *Id.*; *see also Concerned Home Care Providers, Inc. v. Cuomo*, 783 F.3d 77, 88 (2d Cir. 2015) (holding that a severability clause materially identical to this one provided a "clear statutory command" on severability). "Abstention could hardly be justified on the theory that the state court might invent an interpretation at odds with the statute's clear language." *Pharm. Soc'y of State of N.Y., Inc. v. Lefkowitz*, 586 F.2d 953, 957 (2d Cir. 1978).

The circumstances here do not implicate the *Pullman* criteria. The OSA's unequivocal "pass on" prohibition plainly applies to SpecGx, and "a plaintiff asserting federal preemption of an *indisputably applicable* state statute has a clear right to obtain a federal court resolution of its preemption claim." *Fleet Bank, N.A. v. Burke*, 160 F.3d 883, 893 (2d Cir. 1998) (emphasis added).

C. SpecGx's Claims Are Ripe for Review

Next, Defendants claim that SpecGx's constitutional challenges remain prudentially unripe for review because the OSA does not require any surcharge payments to be made until January 1, 2019, and "[a]ny imposition of penalties under the pass-through prohibition could [accordingly] not be imposed until a much later date." Defs.' Mem. 3. But Defendants' position ignores the already existing impacts of the OSA: (i) an outstanding invoice in the amount of $1,256,326.33, which reflects SpecGx's OSA assessment, and (ii) distributors' actions to force SpecGx to bear the full brunt of the OSA's costs. Nor should SpecGx be required to violate the plain language of

the "pass on" prohibition and risk imposition of many millions of dollars in penalties in order to obtain judicial review. These circumstances easily evidence a ripe dispute.

In determining whether to abstain from a case on prudential ripeness grounds, courts proceed with a two-step inquiry, evaluating "[i] the fitness of the issues for judicial decision and [ii] the hardship to the parties of withholding court consideration." *Nat'l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 691 (2d Cir. 2013) (quoting *N.Y. Civil Liberties Union v. Grandeau*, 528 F.3d 122, 131–32 (2d Cir. 2008)). On the issue of fitness, courts consider "whether the issues sought to be adjudicated are contingent on future events or may never occur." *Id.* (quoting *Grandeau*, 528 F.3d at 132). And "[i]n assessing th[e] possibility of hardship, [courts] ask whether the challenged action creates a direct and immediate dilemma for the parties." *Id.* (quoting *Grandeau*, 528 F.3d at 134).

SpecGx's challenges meet each aspect of this inquiry. The deadline for initial surcharge payments is already only six weeks away, and the OSA's provisions—which became effective on July 1, 2018—have already created real-time effects on SpecGx's current participation in the New York pharmaceutical market. *See*, *e.g.*, Compl. ¶¶ 9, 10, 56. As explained in the Complaint, one of the largest national distributors of prescription medications, AmerisourceBergen Corp. ("AmerisourceBergen"), informed SpecGx that it would, effective October 12, 2018, no longer accept opioid product shipments at its National Distribution Center in Columbus, Ohio intended for redistribution to AmerisourceBergen distribution centers in New York, unless SpecGx agreed to shoulder the entire OSA penalty associated with AmerisourceBergen's distributions into New York. *Id.* ¶¶ 9–10. Since the Complaint, the other two of the three major national distributors have pressed the same demand. *See* Supplemental Declaration of Kevin Vorderstrasse in Further Support of Motion for Preliminary Injunction by Plaintiff SpecGx LLC ("Suppl. Vorderstrasse

Decl.") ¶¶ 2–7. More specifically, on November 1, 2018, McKesson Corporation ("McKesson") advised SpecGx of McKesson's "intent to seek reimbursement from SpecGx LLC for the portion of McKesson's Ratable Share that correlates to the SpecGx LLC MMEs that McKesson distributed into New York in 2017." Suppl. Vorderstrasse Decl. Ex. A, at 1. Likewise, in an effort to require SpecGx to make the "first sale" into New York, on November 7, 2018, Cardinal Health ("Cardinal") directed SpecGx "to ship certain opioid-based pharmaceutical products directly to [Cardinal's] distribution centers in New York." Suppl. Vorderstrasse Decl. Ex. B, at 1.

These distributor demands, therefore, make clear that SpecGx must either (i) shortly cease selling its generic opioids in New York (in contravention of the Supremacy Clause), or (ii) shift the financial burden of the OSA to out-of-state purchasers (in violation of the dormant Commerce Clause). In either scenario, the distributors' actions, which are the natural consequence of the OSA, require SpecGx to make significant strategic decisions now. Indeed, SpecGx has already begun planning to stop selling into New York generic opioid products that are subject to the OSA. *See* Suppl. Vorderstrasse Decl. ¶ 11.

Defendants' argument that these issues are not ripe because the "pass on" prohibition has not yet been enforced apparently suggests that SpecGx ignore the plain language of the "pass on" prohibition and subject itself to a multi-million-dollar penalty before raising its challenge. In support, Defendants posit an implausible interpretation of the OSA under which SpecGx *could* pass on the cost of the Ratable Share to New York purchasers of their products, but just not purchasers of *opioid* products. Defs.' Mem. 16–17. For the reasons stated *infra*, however, that strained interpretation of the provision's language is directly contrary to the OSA's legislative history. And it would not, in any event, eliminate the unconstitutional burden that the OSA imposes on the sale of FDA-approved generic pharmaceuticals.

The passage of time will not obviate the constitutional infirmities evident in the legislatively enacted OSA or make the issues implicated by SpecGx's Complaint any "easier or less controversial." *Ahmed v. Cissna*, 327 F. Supp. 3d 650, 668 (S.D.N.Y. 2018) (Failla, J.) (quoting *Simmonds v. INS*, 326 F.3d 351, 357 (2d Cir. 2003)). This matter is eminently fit for review now. *See Clear Channel Outdoor, Inc. v. City of New York*, 608 F. Supp. 2d 477, 506 (S.D.N.Y. 2009) (finding a challenge to the constitutionality of a state rule ripe for review, because the matter presented a legal question, the challenged rule was "final," and presented the plaintiffs with the prospect of immediate hardship), *aff'd*, 594 F.3d 94 (2d Cir. 2010). Indeed, the distributors' efforts to "pass" the OSA's costs back to SpecGx are concrete evidence of the present, immediate hardship of withholding court consideration. *See id.* For these reasons, SpecGx's constitutional challenges to the OSA are plainly ripe for review.

D. SpecGx Possesses Standing to Raise Its Dormant Commerce Clause Claim

Finally, Defendants raise a series of meritless arguments that SpecGx lacks standing to challenge the OSA under the Commerce Clause. Defs.' Mem. 6–9. More specifically, Defendants argue that SpecGx lacks standing (i) to raise injuries on behalf of out-of-state purchasers of opioid medications, *id.* at 7–8; and (ii) to challenge, on Commerce Clause grounds, the OSA's impact on SpecGx's allegedly "intrastate" sales or distributions from its Hobart, New York, manufacturing facility, *id.* at 2, 7–8.[8] Neither argument is availing.

Contrary to Defendants' assertions, SpecGx's causes of action are based on injuries to itself, not to out-of-state purchasers. *See*, *e.g.*, Compl. ¶¶ 73–75, 79–82. As alleged in SpecGx's

[8] Defendants additionally argue that, "inasmuch as [SpecGx's] intrastate and interstate transactions have the same outcome, the Act hardly discriminates against interstate commerce." Defs.' Mem 8 (emphasis omitted). But that argument, which in any event goes to the merits of SpecGx's dormant Commerce Clause challenge rather than SpecGx's standing to assert it, reflects a misperception of the relevant interstate commerce analysis, as expressed below.

Complaint, the OSA makes the sale of generic opioid medications into New York practically and economically infeasible for SpecGx, because those sales would take place at a loss. *See id.* ¶¶ 8, 79. The OSA has already impacted SpecGx's sales to distributors out of state, by leading those distributors to refuse delivery of opioid products destined for sale in New York at their out-of-state locations. *See id.* ¶ 9. And the Complaint alleges that any attempt to pass on the OSA surcharge to out-of-state customers would cause SpecGx to lose sales to those customers. These injuries—which SpecGx specified in its opening papers, *see* Declaration of Kevin Vorderstrasse in Support of Motion for Preliminary Injunction ("Vorderstrasse Decl.") ¶¶ 27–33—are hardly remote or reliant on other parties' injuries. For that reason, Defendants' reliance on the Second Circuit's unpublished decision in *L.A.M. Recovery, Inc. v. Dep't of Consumer Affairs*, 184 F. App'x 85 (2d Cir. 2006), misses the mark. In *L.A.M.*, the Second Circuit found that the plaintiff lacked standing to challenge a New York City regulation under the dormant Commerce Clause, because the plaintiff challenged the regulation solely on behalf of out-of-state towers. *Id.* at 88. Here, by contrast, SpecGx points to injuries it sustains under the OSA in its own right.

SpecGx plainly has standing to seek redress for the "concrete and particularized" harm imposed on SpecGx by the OSA. And even to the extent SpecGx's allegations concern the discriminatory price impacts the OSA creates for sales outside of New York, *see, e.g.*, Compl. ¶ 81, manufacturers "are surely entitled to litigate whether the discriminatory [surcharge] has had an adverse competitive impact on their business,"[9] *Bacchus Imps., Ltd. v. Dias*, 468 U.S. 263, 267 (1984) (holding that wholesale liquor distributors had standing to challenge tax on out-of-state liquor even though they could pass it on to customers); *cf. Gen. Motors Corp. v. Tracy*, 519 U.S.

[9] Courts have, for that very reason, routinely considered Commerce Clause challenges under closely matched circumstances. *See, e.g.*, *Freedom Holdings, Inc. v. Spitzer*, 357 F.3d 205 (2d Cir. 2004); *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664 (4th Cir. 2018).

278, 286 (1997) ("[C]ognizable injury from unconstitutional discrimination against interstate commerce does not stop at members of the class against whom a State ultimately discriminates . . . .").

Likewise unavailing is Defendants' argument that SpecGx's sales or distributions subject to the OSA are beyond the purview of the dormant Commerce Clause because they originate from SpecGx's Hobart, New York, manufacturing facility and are thus entirely intra-state transactions. Defs.' Mem. 7–8. This is not accurate. Many of the products on which SpecGx is being forced to bear the brunt of the ratable share (by consequence of the OSA's "pass on" prohibition) were distributed by SpecGx to out-of-state distributors, which, in turn, made the first sale into New York State. In any event, Defendants' argument misconceives SpecGx's dormant Commerce Clause argument, which is premised on the fact that if in-state sales (regardless of whether they are from the Hobart facility or elsewhere) become economically infeasible, SpecGx could be forced to recover the cost of the Ratable Share from out-of-state purchasers, in order to avoid selling at a loss. SpecGx has standing to make that dormant Commerce Clause claim, because those out-of-state transactions do take place in interstate commerce.[10]

Accordingly, the Defendants' standing arguments should be rejected.

II. SPECGX HAS STATED STRONG CHALLENGES TO THE OSA THAT ARE LIKELY TO SUCCEED AND EASILY SURVIVE A MOTION TO DISMISS

Defendants do not seriously challenge the fundamental premise of SpecGx's constitutional claims—namely, that the OSA forces generic manufacturers to sell their opioid medications at a

[10] For that reason alone, *Coalition for Competitive Electricity v. Zibelman*, 906 F.3d 41 (2d Cir. 2018), offers no support for Defendants' position. As Defendants rightly note, *Zibelman* addresses the unremarkable proposition that, for purposes of "standing for their dormant Commerce Clause claim, [p]laintiffs must demonstrate that their alleged injuries are traceable to discrimination against interstate commerce." *Id.* at 58. SpecGx plainly meets that threshold, because its dormant Commerce Clause claim relies on the OSA's "practical effect" on out-of-state transactions.

loss in New York. This forces one of two outcomes—either they will stop selling in New York (in contravention of federal rights embodied in the Hatch-Waxman Amendments) or else push the costs out of the state (in contravention of the dormant Commerce Clause). These challenges both state claims for relief under Rule 12(b)(6), and they are likely to succeed, in satisfaction of the standard for preliminary injunctive relief.

A. SpecGx's Claim that the OSA Is Preempted by the Hatch-Waxman Amendments Is Likely to Succeed

1. The OSA Effectively Prohibits the Sale of Generic Opioid Medications, Frustrating the Express Federal Purpose of the Hatch-Waxman Amendments

SpecGx's preemption claim rests on a simple premise: that the OSA operates to *prevent* precisely what the federal government has expressly sought to *promote*, which the Supremacy Clause forbids New York to do. Where, as here, the state law "frustrate[s] the accomplishment of a federal objective," that state law must be set aside. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). Defendants fail genuinely to challenge either that the purpose of the Hatch-Waxman Amendments is to encourage the availability of low-cost generic medications, or that the OSA undermines that purpose by making it infeasible to sell generic opioids in New York. Therefore, SpecGx has stated a viable claim that the OSA is preempted by the Hatch-Waxman Amendments, and that claim is likely to succeed.

First, Defendants do not dispute the basic facts underlying SpecGx's preemption claim—namely, that the OSA would force SpecGx to sell generic opioid products *at a loss* in New York.[11]

[11] In the Declaration of Seth Farber, he submits that the Defendants are not in a position to confirm the accuracy of Kevin Vorderstrasse's declaration. Farber Decl. ¶ 3. This is not true: the foregoing analysis was based on data from publicly available sources—namely SpecGx's report submitted to the DOH, DOH's calculation of SpecGx's Ratable Share, and publicly available AMP data. Defendants have not contested any of these data nor the calculations based on the data reflected in Mr. Vorderstrasse's declaration. Accordingly, because Defendants have not challenged these facts, they can serve as the basis of this Court's decision on SpecGx's motion for preliminary

SpecGx's moving papers demonstrated that the Ratable Share per MME exceeds the AMP per MME for two of the three highest volume generic opioid medications sold by SpecGx that are subject to the OSA; for the third of these high-volume products, the very small amount by which the AMP per MME exceeds the Ratable Share per MME would not even cover the costs of production and distribution. Mem. of Law in Supp. of Mot. for Prelim. Inj. at 10; Vorderstrasse Decl. ¶¶ 21–23, 26. And, by its plain terms, the OSA prohibits SpecGx from passing on the Ratable Share to the purchasers of those products in New York. N.Y. Pub. Health § 3323(2) ("No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid . . . ."). Accordingly, under the terms of the OSA, SpecGx loses money on every sale that SpecGx makes of these generic opioid products into New York. Basic economic reality dictates that if generic manufacturers are guaranteed to lose money on the sale of their generic opioid products, they will abandon the New York opioid market completely. And SpecGx is already making plans to do so. The inescapable conclusion is thus that the OSA will ultimately *reduce*, if not eliminate entirely, the availability of generic opioid medications in New York.

Second, Defendants acknowledge—and SpecGx agrees—that the Congressional intent of the Hatch-Waxman Amendments is to "provide affordable generic pharmaceutical products *to patients*." Defs.' Mem. 13.[12] It follows, then, that the OSA poses an obstacle to accomplishing this Congressional objective by *reducing* patients' access to affordable generic pharmaceutical products, whereas Congress sought to *expand* such access. *See In re Methyl Tertiary Ether (MBTE) Prods. Liab. Litig.*, 725 F.3d 65, 102 (2d Cir. 2013).

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injunction, even if defendants remain able to contest those facts at a later stage of the proceedings. *Visual Scis., Inc. v. Integrated Commc'ns Inc.*, 660 F.2d 56, 58 (2d Cir. 1981).

[12] Defendants falsely claim that SpecGx's position is that Congress's intent is "to benefit the manufacturers and distributors of such products." Defs.' Mem. 13.

Along the same lines, it is irrelevant that the Hatch-Waxman amendments regulate "patent issues, drug approvals, [and] labelling" whereas the OSA imposes (according to the Defendants) "taxes on generic drugs." Defs.' Mem. 9. What matters is that the *purpose* of those federal regulations, as expressed by Congress, is "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647; *see also Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1282 (Fed. Cir. 2008) (noting Hatch-Waxman was designed to bring low-cost generic drugs to market). Nor are the objectives and purposes of the *state law* in question relevant to a Supremacy Clause analysis. That the OSA's objectives to generate revenue for opioid abuse public health and education are supposedly consistent with the objectives of other federal programs, Defs.' Mem. 13, cannot negate the fact that the operation of the OSA frustrates Congressional intent vis-à-vis the Hatch-Waxman Amendments. What is more, the federal government has also specifically deliberated as to the access and availability of *opioid* medications through the Comprehensive Drug Abuse Prevention and Control Act of 1970. Pub. L. No. 91-513, 84 Stat. 1236 (codified as amended at 21 U.S.C. §§ 801–971 (2012)). Pursuant to this federal legislation, the Drug Enforcement Agency ("DEA") sets nationwide annual production quotas for Schedule II opioids, like those subject to the OSA, based on anticipated medical, scientific, research, industrial, and export needs. 21 U.S.C. § 826(a). The DEA then grants annual procurement quotas to registered manufacturers, like SpecGx. *Id.* § 826(b). Accordingly, DEA has endorsed that there is a legitimate need for the volume of opioids produced by SpecGx—including for those sold and distributed in New York.

2. Defendants Cannot Avoid the Preemption Claim by Rewriting the "Pass On" Prohibition

Rather than contesting SpecGx's factual evidence that the Ratable Share per MME is so high that it exceeds the sales price, Defendants instead urge that there is a "plausible" reading of

the "pass on" prohibition that would allow SpecGx to recover the Ratable Share from its New York operations. In the context of discussing irreparable harm (rather than the merits of the preemption claim), Defendants suggest that it is "plausible" to read the "pass on" prohibition as prohibiting only passing on the cost of the Ratable Share to in-state purchasers of *opioid medications*. Defs.' Mem. 16. Under this creative reading, SpecGx would be free to pass the cost of the Ratable Share to in-state purchasers of other medications or products, and thereby avoid spreading the costs out-of-state. As an initial matter, this alternative interpretation does not resolve the preemption problem. Forcing generic manufacturers to increase the prices of their other products makes those other products less competitive, and thus still impairs generic manufacturers' ability to compete in the market, which frustrates the goals of the Hatch-Waxman Amendments.

In any event, Defendants' novel interpretation of the "pass on" prohibition cannot be squared with its text or purpose. To begin, the plain language of the OSA cannot sustain that reading. Section 3223(c)(2) of the OSA states that "No licensee shall pass the cost of their ratable share amount to *a purchaser*, including the ultimate user of the opioid." (emphasis added). The term "a purchaser" is not limited at all to a purchaser of opioids. Likewise, Section 3223(10)(c) provides that "[w]here a ratable share, or any portion thereof, has been passed on to *a purchaser* by a licensee, the commissioner may impose a penalty not to exceed one million dollars." Here too, the term "a purchaser" is not limited to "a purchaser of opioids." Accordingly, the plain text offers no support for the Defendants' proposed interpretation.[13]

Second, the legislative history is crystal clear on this point: the legislature wanted manufacturers and distributors to pay the Ratable Shares, *not* New York pharmacies or

[13] Indeed, even Defendants' paraphrase of the "pass on" prohibition indicates that it is as broad as the plain text indicates: "The Act does not permit the surcharge to be passed directly on to patients or to end users." Defs.' Mem. 4.

consumers.[14] Pushing the costs off to in-state consumers of *other* pharmaceutical products contradicts this intention. Notably, the initial version of the OSA was the subject of opposition from pharmacies precisely because of the burden it would place on their business. Joint Legis. Budget Hearing on Health/Medicaid, 2018–19 Leg. (N.Y. 2018) (statement of Chain Pharmacy Association of NYS) (explaining that the surcharge "could force some pharmacies to make service reductions or close"); *id.* (statement of Roxanne Richardson, President, Pharmacist Society of the State of New York) (opposing the surcharge because "[p]harmacies are . . . in no position to pay"). The pharmacies worried because there were a number of scenarios where they would make the first sale in-state. *Id.* (statement of Chain Pharmacy Association of NYS). But Commissioner Zucker made clear that this was not the intent of the Act: "[T]he way we put this forward is to make sure it's *at the highest level* . . . —that the [then-]tax would be at the [pharmaceutical] companies . . . . [T]hey are the ones who . . . need to be held accountable to it." Joint Legis. Budget Hearing on Health/Medicaid, 2018–19 Leg. (N.Y. 2018) (emphasis added). The OSA was revised to narrow the definition of "distributor" to exclude "administering or dispensing to the ultimate user," N.Y. Pub. Health Law § 3323(1)(c), to protect pharmacies from paying any part of the opioid stewardship fund. Under Defendants' construction of the "pass on" prohibition, the statute would allow precisely what it was designed to avoid—manufacturers passing the cost of the Ratable Share on to the pharmacies that buy the opioid medicines (though doing so under the

[14] *See*, *e.g.*, N.Y. Assembly Mar. 30, 2018 ("MR. RAIA: Now, how on earth are we going to determine whether or not these costs are being turned—turned up, passed on to the consumer? . . . MS. WEINSTEIN: Well, the—the language does say that the assessment would be prohibited from being passed along to consumers. And as I said, a pen—financial penalty of roughly $1 million per—per incident would be levied for attempting to pass along the cost of the assessment to downstream purposes.").

guise that it is a "charge" on non-opioid products the pharmacies also buy). Nothing supports Defendants' strained reading.

Defendants also hint that DOH's regulatory guidance may provide relief from enforcement of the "pass on" prohibition's express language. They misleadingly paraphrase the regulatory guidelines, stating that the guidelines provide that the "pass on" prohibition "is not intended to penalize the licensees for recovering their operating costs in their overall pricing scheme." Defs.' Mem. 4. But the guidelines say nothing of the sort. Rather they say that the "pass on" prohibition is "not intended to apply to price increases that are attributable to other ordinary changes in manufacture or distribution costs."[15] The only change in manufacture or distribution cost is the OSA, the recoupment of which the "pass on" prohibition expressly bars. The guidelines cannot be read to permit precisely what the OSA expressly prohibits.

3. The OSA Conflicts with Federal Law Because It Frustrates the Objectives of the Federal Law; "Actual Conflicting Legal Requirements" Are Not Necessary to Show Preemption

Defendants erroneously insist that federal preemption occurs only when there is an "actual impediment to doing business" such as "actual conflicting legal requirements." Defs.' Mem. 13. As an initial matter, the OSA is, in fact, an "actual impediment" to selling generic opioid medications in New York, as no manufacturer can feasibly—or would rationally—continue to sell a product if it must pay a surcharge on each sale that exceeds the price the manufacturer receives. Moreover, obstacle preemption does not require "actual conflicting legal requirements." Defs.' Mem. 13. As the Supreme Court has held, "state laws and regulations may conflict with a federal statute, whether because a private party cannot comply with both sets of provisions *or because the*

[15] N.Y. Dep't of Health, New York State Opioid Annual Assessment Reporting Guidance (2018), https://www.health.ny.gov/professionals/narcotic/opioid_stewardship_act/docs/osa_reporting_guidance_document.pdf.

objectives of the federal statute are frustrated." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 n.6 (2000) (emphasis added); *see also CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 663 (1993) ("Where a state statute . . . frustrates[] federal law, the former must give way."). Here, "the objectives of [Hatch-Waxman] are frustrated" by the OSA not because it imposes inconsistent legal obligations, but because the inevitable outcome of the OSA is to nullify the favorable effects of the Hatch-Waxman Amendments in New York with respect to making lower cost generic opioids available to patients.

As discussed in SpecGx's preliminary injunction memorandum, the state law in *Geier* did not impose "conflicting legal requirements" nor was it an "actual impediment to doing business." The "all airbag" standard could coexist with the federal standard that provided for airbag alternatives, yet the state standard imposed an obstacle to Congressional policy goals of achieving improved safety through a variety-based approach. *Geier*, 529 U.S. at 881.[16] Similarly here, while a practical ban on the sale of generic drugs in New York *could* coexist with the Hatch-Waxman Amendments, it indisputably frustrates the objectives of those Amendments, which depend on the actual availability of low-cost generic products.

This case is on all fours with *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315 (Fed. Cir. 2017). There, with direct reference to a Hatch-Waxman analog, the Federal Circuit recognized that a "[c]onflict in *technique* can be fully as disruptive to the system Congress erected as conflict in overt policy." *Id.* at 1329 (alteration in original) (emphasis added) (quoting *Amalgamated Ass'n of St., Elec. Ry. & Motor Coach Emps. of Am. v. Lockridge*, 403 U.S. 274, 287 (1971)). *Amgen* concerned the Biologics Price Competition and Innovation Act (BPCIA), which "has certain

[16] *Cf. Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 721 (1985) (noting that "overly restrictive local legislation" that threatens the supply of an FDA-approved product would be preempted if Congress intended to ensure the availability of it).

similarities in its goals and procedures as [the Hatch-Waxman Amendments]," in that it provides for "an abbreviated pathway for regulatory approval" of "highly similar" biological products (*e.g.*, vaccines, blood components, tissues). *Id.* at 1320. The Federal Circuit held that the BPCIA preempted California's Unfair Competition Law, reasoning that the state's legal standards—although not *actually* conflicting—would "'dramatically increase the burdens' on biosimilar applicants beyond those contemplated by Congress in enacting the BPCIA." *Id.* at 1329 (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)). And, given that Congress made a "deliberate" policy choice concerning approval of biosimilar products, imposing additional burdens would "interfere with the careful balance struck by Congress." *Id.* (quoting *Arizona v. United States*, 567 U.S. 387, 405–06 (2012)).

So too here. Although the OSA does not directly impact FDA approval of generic products, it does directly impact the availability of such products to consumers. The OSA would dramatically *increase* the financial burdens on manufacturers of generic opioid medications where Congress sought to *decrease* the financial and regulatory burdens on generic pharmaceuticals in order to increase their availability for patients. The financial burdens imposed on generic manufacturers by the OSA are oppressive: the OSA does not merely cause a reduction in profits, as Defendants repeatedly assert, *see* Defs.' Mem. 13, 15, 18, but effectively forces manufacturers to sell generic opioid medications *at a loss*—such that it becomes economically infeasible to sell these generic products. As such, like the state law in *Amgen*, the OSA is preempted by the Hatch-Waxman Amendments.

4. This Court Need Not Defer to the State's Police Powers

A state cannot wield its police powers to undo federal policies and frustrate federal objectives. *See Geier*, 529 U.S. at 907. Defendants cite *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 (1997), for the proposition that the "historic police powers of the

State include the regulation of matters of health and safety," and exercise of those powers creates a presumption against preemption. *De Buono* resolved whether a generally applicable tax on local hospitals violated ERISA's express preemption provision. The tax on the hospitals at issue only imposed "some burdens" on ERISA, and therefore the Supreme Court held that ERISA's express preemption provision was inapplicable. *De Buono*, 520 U.S. at 815. Here, however, for the reasons stated *supra*, the OSA imposes *significant* burdens on the federal objectives of Hatch-Waxman by making it infeasible to sell a product that federal law expressly sought to promote. Where, as here, a state law frustrates federal policies and objectives (even if related to health and safety), that state law must be preempted. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477 (2013) (finding preemption of state common-law duty regarding health and safety where it conflicted with the FDCA); *Geier*, 529 U.S. at 873 (holding that D.C. vehicle safety law preempted by the National Traffic and Motor Vehicle Act of 1966); *Boggs v. Boggs*, 520 U.S. 833, 840–41, (1997) (finding preemption of state community property law that "implement[s] policies and values lying within the traditional domain of the States" where it undermined the purposes and objectives of ERISA); *S & R Dev. Estates, LLC v. Town of Greenburgh*, No. 16-CV-8043, 2018 WL 4119188, at *8 (S.D.N.Y. Aug. 29, 2018) ("[E]ven though property law is an area occupied 'by the historic police powers of the state,' the relief that the Sisters request conflicts with Congress's 'manifest purpose' in passing the FHA, and as a result any presumption against preemption is overcome." (citations omitted)).

Further, Defendants' attempt to paint the OSA as merely an unremarkable "tax" that may simply make the sale of generic opioids less profitable is woefully incomplete. This is not a "tax"—or any other imposition—that merely depresses sales by increasing the price of the product. The Ratable Share is a penalty that exceeds the sales price of many of these products. In

conjunction with the "pass on" prohibition, the OSA functions as a practical *prohibition* on sales of generic opioid products, as no rational economic actor would sell at a loss. Such a prohibition severely frustrates the express goals of the Hatch-Waxman Amendments. Where a state law, regardless of the nature of that law, works to undercut a federal purpose or objective, that state law must be preempted. *See*, *e.g.*, *CSX Transp*, 507 U.S. at 663; *Geier*, 529 U.S. at 873.

B. SpecGx Is Likely to Succeed on Its Claim that the OSA Violates the Dormant Commerce Clause

Again, Defendants do not directly address the merits of SpecGx's dormant Commerce Clause claim and do not seem to dispute at all the core of SpecGx's argument—that should SpecGx and other Licensees under the OSA be forced to spread the costs of their Ratable Share payments out-of-state, this would compel price changes in markets beyond New York's boundaries, which is *per se* invalid under dormant Commerce Clause. As the Supreme Court held in *Healy v. Beer Institute*, the dormant Commerce Clause forbids the adoption of state "legislation that has the practical effect of establishing 'a scale of prices for use in other states.'" 491 U.S. 324, 336 (1989); *see also Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 580 (1986); *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 669 (4th Cir. 2018) ("*AAM*").

The OSA creates the same "practical effect." The imposition of the Ratable Share penalty, as explained *supra*, makes the sale of generic opioids into New York practically and economically unfeasible *unless* generic manufacturers shift the burden of paying the assessment to purchasers and patients residing out-of-state. Given that the Ratable Share per MME exceeds the price of many of the highest volume products and that the OSA's "pass on" prohibition precludes manufacturers and distributors from recouping the cost of their Ratable Share (or any portion thereof) from in-state New York purchasers, the only way generic manufacturers can continue to sell generic opioid medications in New York without losing on every sale is if they spread the

costs *out-of-state*. In this way, just like statutes in *Healy*, *Brown-Forman*, and *AAM*, the OSA's combination of the Ratable Share penalty and "pass on" prohibition "has the undeniable effect of controlling commercial activity occurring wholly outside the boundary of the State." *Healy*, 491 U.S. at 337; *see also Brown-Forman*, 476 U.S. at 583; *AAM*, 887 F.3d at 671.

In an effort to rebut the application of the dormant Commerce Clause here, Defendants raise an inapposite case, *National Electrical Manufacturers Ass'n v. Sorrell*, 272 F.3d 104 (2d Cir 2001). But far from supporting Defendants' cause, *Sorrell* suggests that this is exactly the sort of case that *would* violate the dormant Commerce Clause. *Sorrell* involved a Vermont statute that required labels on lamps containing mercury bulbs. The lampmakers sought an injunction on dormant Commerce Clause grounds, but the Second Circuit disagreed because the manufacturers could "pass much of the increased costs along to Vermont consumers in the form of higher prices." *Id.* at 110. The Second Circuit expressly distinguished circumstances—as with the OSA—where "the state necessarily prevented firms from recouping any of the costs imposed by the state statute from the residents of the state itself" from the statute in *Sorrell* where the "manufacturers remain[ed] free to charge higher prices only to Vermonters without risking violation of the statute." *Id.*; *see also id.* at 111 (suggesting that "the Commerce Clause would prohibit" state control of "the opportunity cost of capital, their individual production costs, and what the demand in the state will bear" with regard to a regulation). The OSA violates the dormant Commerce Clause in precisely the fashion described in *Sorrell*.

Even more, rather than seriously dispute this extraterritorial effect, Defendants implicitly embrace it. To suggest that SpecGx can afford to "eat" the losses on their New York sales of generic opioids, Defendants point to the overall profitability of the Hobart, New York, facility. Defs.' Mem. 2, 7. That profitability is mostly attributable to out-of-state sales. Defendants are

thus effectively suggesting that SpecGx should recoup the surcharge from its non–New York customers. That is the natural and expected consequence of the combination of a "surcharge" that exceeds the product's price and prohibition against collecting the surcharge from New York purchasers. The *only* alternative to ceasing sales is passing the surcharge on to out-of-state purchasers. As the saying goes, if you are selling at a loss, you cannot "make it up on volume."

The only alternative Defendants raise, in an off-hand way, is to read the "pass on prohibition" as only prohibiting passing on the Ratable Share to in-state purchasers of opioid medications. For the reasons explained *supra*, that reading is untenable in light of the plain language and legislative history.

Finally, Defendants do not address SpecGx's alternative argument that the burden this places on interstate commerce is clearly excessive in relation to the putative local benefits. As explained in SpecGx's opening brief, the *Pike* balancing test prohibits state laws that create a burden on interstate commerce in excess of the putative local gains. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970). The OSA's costs to interstate commerce "clearly" exceed the putative local gains, because the OSA shifts *all* of its financial burdens onto non-New York residents, ostensibly in the interests of funding *existing* initiatives within New York, which benefit only residents of New York.

III. THE REMAINING PRELIMINARY INJUNCTION FACTORS ARE SATISFIED

A. SpecGx Will Suffer Irreparable Harm Absent an Injunction

Ignoring the robust authority SpecGx relied on in its opening brief, Defendants describe SpecGx's claims of an indisputable constitutional injury and the need to exit the New York market as "erroneous" and "baseless." Defs.' Mem 16. Not so.[17] In the absence of injunctive relief,

[17] Given what is at stake—the availability to patients of FDA-approved medications, in amounts approved by the DEA as serving legitimate medical purposes—it is not a trifling matter for

SpecGx will, in the *very near* future, be forced to pay an *unconstitutional* Ratable Share (along with accruing Ratable Shares for its assessable products sold by its three major distributors, *see supra* Part I.C). This unconstitutional outcome is irreparable harm in its own right. *See Conn. Dep't of Envtl. Prot. v. Occupational Safety & Health Admin.*, 356 F.3d 226, 231 (2d Cir. 2004) (noting an "alleged violation of a constitutional right triggers a finding of irreparable injury" (citation omitted)). And even if it were not, the OSA has forced SpecGx to make significant business decisions about exiting the New York market as a result of the OSA that will inevitably—and imminently—result in *both* monetary (*i.e.*, payment of the unconstitutional Ratable Share) and nonmonetary harm (*i.e.*, interference with long-standing contractual relationships with nationwide distributors, loss of reputation, goodwill and business opportunities). The confluence of these overlapping effects on SpecGx unquestionably constitutes irreparable harm—especially because, in the absence of an injunction, the Eleventh Amendment would preclude SpecGx from obtaining monetary relief for its injuries, *see, e.g.*, *Edelman v. Jordan*, 415 U.S. 651, 663 (1974), including irreparable injury to its relationships with distributors or SpecGx's goodwill and market reputation.

Defendants fail to acknowledge, much less distinguish, the long line of Second Circuit decisions emphasizing that "the *alleged* violation of a constitutional right triggers a finding of irreparable injury." *Conn. Dep't of Envtl. Prot.*, 356 F.3d at 231 (emphasis added) (citation omitted) (presuming irreparable harm in the face of a federal agency's claim of an alleged violation of its constitutional sovereign immunity); *accord Lynch v. City of New York*, 589 F.3d 94, 99 (2d Cir. 2009) (applying the same presumption in the face of an alleged violation of the Fourth Amendment); *Statharos v. N.Y.C. Taxi & Limousine Comm'n*, 198 F.3d 317, 322 (2d Cir. 1999)

Defendants to propose, without any evidentiary basis, to test the proposition that generic manufacturers would continue selling these critical products in New York at a loss, rather than follow the economically rational course of ceasing sales into New York.

(applying the same presumption in the face of an alleged violation of the constitutional right to privacy); *Am. Libraries Ass'n v. Pataki*, 969 F. Supp. 160, 168 (S.D.N.Y. 1997) ("Deprivation of the rights guaranteed under the Commerce Clause constitutes irreparable injury.").

And even Defendants' own cherry-picked authorities demonstrate that SpecGx satisfies the test for irreparable harm. Defendants point to *Smith v. Fredrico*, No. 12-4408, 2013 WL 122954 (E.D.N.Y. Jan. 8, 2013), for the premise that a constitutional deprivation must "involve[] non-compensable injuries *in addition* to money damages" to be irreparable. Defs.' Mem. 16. But SpecGx easily satisfies that condition, as demonstrated by the injury to SpecGx's business relations if it exits the New York market, as it is already planning to do in the absence of an injunction.[18] *See infra*.

The imminent enforcement of the OSA—through SpecGx's *outstanding* invoice due January 1, 2019, and the *ongoing* accrual of Ratable Share payments going forward—will (and has) caused irreparable injury to SpecGx beyond monetary losses. Given that SpecGx will be forced to sell generic opioid medications at an economic loss, SpecGx plans to exit the New York market. More than a mere "inconvenien[ce]," as Defendants characterize it, Defs.' Mem. 18, exiting the market will damage SpecGx's relationships with nationwide distributors and sacrifice years of built-up goodwill. None of these imminent harms can be remedied after-the-fact and each therefore constitutes irreparable injury. *See Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 404 (2d Cir. 2004).

[18] In addition, *Smith* proves easily distinguishable. There, the court denied an injunction seeking the return of seized property, given the availability of after-the-fact monetary relief. 2013 WL 122954, at *6. Here, by contrast, sovereign immunity will preclude SpecGx from obtaining *any* after-the-fact reimbursement for the unconstitutional assessment due January 1, 2019.

And the unusual monetary losses SpecGx will endure under the OSA only augment the non-monetary harms,[19] because, unlike suits against private entities, SpecGx will have no after-the-fact mechanism to recovery the *millions of dollars* in losses. *See Kansas by & Through Kansas Dep't for Children & Families v. SourceAmerica*, 874 F.3d 1226, 1251 (10th Cir. 2017) ("[A] party suing the government suffers irreparable harm where 'monetary relief might not be available . . . because of the [government's] sovereign immunity.'" (omission and second alteration in original) (quoting *Prairie Band of Potawatomi Indians v. Pierce*, 253 F.3d 1234, 1250 (10th Cir. 2001))); *accord United States v. State of New York*, 708 F.2d 92, 94 (2d Cir. 1983) (recognizing that sovereign immunity issues may provide a basis for the issuance of prospective, injunctive relief). In other words, "financial compensation," Defs.' Mem. 19, will simply be unavailable to SpecGx, which is why SpecGx pursued prospective equitable relief under *Ex parte Young*. *See generally* Compl. And, even more importantly, these non-recoverable out-of-pocket monetary losses are significant: the total Ratable Share for all of SpecGx's opioid medications sold into New York—both by SpecGx and by distributors—will exceed SpecGx's total revenues for the sale of such products, meaning that these sales will occur *at a loss*. *See* Vorderstrasse Decl. ¶ 33.

Given the constellation of these circumstances—the constitutional injury, non-monetary harms, and non-recoverable monetary harms—SpecGx has plainly established irreparable harm in the absence of an injunction.

[19] Defendants suggest, without basis, that SpecGx could avoid or minimize these constitutional injuries, by "distribut[ing] their ratable shares amongst all *other* drug purchases (*i.e.*, non-opioid sales), both in and outside of New York." Defs.' Mem. 17. Aside from being practically impossible, Defendants' proposal cuts against the OSA's express text and thus would not avoid any unconstitutional injury.

B. The Balance of Equities Favors SpecGx and a Preliminary Injunction Is in the Public Interest

Defendants argue that the balance of hardships militates in their favor, because the OSA "fund[s] critically needed opioid treatment and education services" and SpecGx "cannot reasonably dispute the value of such programs." Defs.' Mem. 19. SpecGx, of course, supports efforts designed to discourage the diversion of FDA-approved generic opioid medications. But Defendants (and the State of New York) can suffer *no* harm from the issuance of an injunction that preserves the status quo by preventing the implementation of an unconstitutional statute. *See N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013) (explaining that the state has *no* "interest in the enforcement of an unconstitutional law"); *New York ex rel. Spitzer v. Cain*, 418 F. Supp. 2d 457, 473 (S.D.N.Y. 2006) (noting that there "can be no irreparable harm to a municipality when it is prevented from enforcing an unconstitutional statute"). Likewise, Defendants' assertion that an injunction would somehow impair "critical[]" funding is, as an initial matter, belied by the OSA's legislative history, which plainly reflects the State's intention to use the fund created by the OSA to supplant *existing* state funding. *See* Conniff Decl. Ex. M. But even more, SpecGx's specific constitutional claims would be remedied by enjoining only the "pass on" prohibition, and Defendants acknowledge the OSA has a severability clause.[20] In this way, SpecGx's challenge does not actually interfere with the state's ability to collect Ratable Shares and furnish the Opioid Stewardship Fund for the existing DOH programs. On the other hand, the significant harms caused to SpecGx through the implementation and enforcement of the OSA, by contrast, are severe not only to SpecGx, but the entire market. *See* Vorderstrasse Decl. ¶¶ 27–33; Mem. of Law in Supp. of Pl.'s Mot. for Prelim. Inj. Ex. 1, ¶ 11, *Ass'n for Accessible Medicines v.*

[20] In the event this Court concludes that the "pass on" prohibition is not severable, this would only serve to underscore HDA's argument that the OSA was adopted as a legislative *punishment* to manufacturers without due process of law. HDA Mem. 22–25, 30–32.

Underwood, No. 18-cv-08180 (S.D.N.Y. Sept. 7, 2018); *id.* Ex. 2, ¶ 11; *id.* Ex. 3, ¶ 12; *id.* Ex. 4, ¶ 10. The balance of hardships strongly favors the issuance of an injunction.

While Defendants dismiss as "speculative" SpecGx's analysis that the OSA "will undermine" the availability of generic opioid medications, Defs.' Mem. 19, to the contrary, it is Defendants' bare assertion that generic opioid will *remain* on the market that is entirely speculative and devoid of either factual or logical support. As noted, Defendants do not contest the base fact that the OSA surcharge exceeds even the wholesale *price*, and even more so any profit, on the sale of generic opioids. Defendants offer *no* basis to believe that generic opioids would remain on the market if manufacturers incur a *loss* on each sale of those products into New York. In contrast to the absence of any evidence supporting Defendants' counter-intuitive theory, SpecGx has stated unequivocally that it has begun steps to exit the New York generic opioid market if the OSA is not enjoined.[21] *See* Vorderstrasse Decl. ¶ 33; Suppl. Vorderstrasse Decl. ¶ 11. The public interest in lower cost generic opioid medications, as determined by Congress in the Hatch-Waxman Amendments and DEA in ascertaining the legitimate demand for opioids, forecloses an argument by Defendants that the public interest would be served by eliminating those generic opioid products from the market. In the case of conflict between state law and the Federal constitution and policy, vindication of federal rights serves the public interest. *See Ligon v. City of New York*, 925 F. Supp. 2d 478, 541 (S.D.N.Y. 2013) ("[T]he public interest lies with the enforcement of the Constitution."). And the State has *no* "interest in the enforcement of an unconstitutional law," like the OSA. *N.Y. Progress & Prot. PAC*, 733 F.3d at 488.

[21] *See* Mem. of Law in Supp. of Pl.'s Mot. for Prelim. Inj. Ex. 1–5, *Ass'n for Accessible Medicines*, No. 18-cv-08180 (Sept. 7, 2018).

For these reasons, the balance of equities and the public interest decidedly support SpecGx's request for preliminary relief.

CONCLUSION

For the foregoing reasons and those set forth in the related actions, SpecGx respectfully requests that Defendants' motion to dismiss be denied in its entirety and that SpecGx's motion for preliminary injunction be granted in all respects.

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CERTIFICATE OF SERVICE

I, Douglas H. Hallward-Driemeier, hereby certify that the foregoing document, Plaintiff SpecGx LLC's Combined Opposition to Defendants' Motion to Dismiss and Reply in Support of its Motion for Preliminary Injunction, filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 15th day of November, 2018.

/s/ Douglas H. Hallward-Driemeier
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